ICMRA-industry virtual workshop on
Development of a Pharmaceutical Quality Knowledge Management System
Thursday, July 20, 2023
7:00 – 10:00 ET | 13:00 – 16:00 CET
AGENDA

7:00 – 7:05 **ICMRA welcoming remarks**
Emer Cooke, EMA and Chair ICMRA

7:05 – 7:10 **Industry welcoming remarks**
Greg Perry, IFPMA

7:10 – 7:25 **ICMRA presentation**
"Background to the ICMRA Pharmaceutical Quality Knowledge Management System project and progress to date"
Lorraine Nolan, HPRA
Description: In this session, regulators will provide an overview of the background to the ICMRA PQ KMS project, in addition to updates on progress made to date, ongoing work packages, and future plans.

7:25 – 7:35 **Industry presentation**
"Industry's perspective on ICMRA's Global Strategy & Pilots for PQ KMS"
Ginny Beakes-Read, Amgen (IFPMA)
Description: In this presentation, industry will provide their perspective on topics relevant to the PQ KMS project and will speak to their engagement with, and involvement in, the ongoing PQ KMS pilots.

7:40 – 7:45 **Introduction to Panel 1**
Evangelos Kotzagiorgis, EMA
Description: A brief presentation will provide an overview of the ongoing pilot looking at collaborative assessment of post-approval change management protocols (PACMPs).

7:45 – 8:45 **Panel 1: Pilot of collaborative assessment of post-approval change management protocol**
Co-moderated by Mónica Perea-Vélez, GSK (Vaccines Europe), and Theresa Mullin, FDA

Panellists: Regulators	***Panellists: Industry***
Larry Lee, FDA	*Christine Wu, Roche*
Yasuhiro Kishioka, PMDA	*Diane Wilkinson, AstraZeneca*
Evdokia Korakianiti, EMA	*Nina Cauchon, Amgen*
Susan Polifko, FDA	*Sylvie Meillerais, MSD*
Ranjit Thomas, FDA	*Wan-Li Liao, Merck/ EMD Serono*

Description: Panellists will discuss their experiences with the collaborative assessment pilot, looking at the benefits, challenges and learnings gained through participation in the pilot to date. Panellists will also look at potential barriers to participation, and explore practical solutions to those barriers, along with next steps for the pilot and plans to support sustainable and achievable implementation of collaborative assessment of post-approval changes.

This workshop was jointly organised by ICMRA and IFPMA, including ICH, IPRP, PIC/S, ABPI, BIO, DCVMN, EFPIA, IGBA, JPMA, Medicines Australia, PhRMA, and Vaccines Europe

8:40 – 8:45 **Introduction to Panel 2**
Stelios Tsinontides, FDA
Description: A brief presentation providing an overview of the ongoing collaborative hybrid inspection pilot (CHIP).

8:45 – 9:45 **Panel 2: Collaborative hybrid inspection pilot**
Co-moderated by Nick Cappuccino, IGBA, and Theresa Mullin, FDA

Panellists: Regulators	***Panellists: Industry***
Stelios Tsinontides, FDA	*Fabian Welte, Roche*
Brendan Cuddy, EMA	*Tim Watson, Gilead*
Magda Joseph, Health Canada	*Matt Popkin, GSK*
Christian Schärer, Swissmedic	

Description: Panellists will discuss their experiences with the collaborative hybrid inspection pilot, looking at the learnings gained through participation in the pilot to date, and discussing how best to carry out such inspections, including the associated practical considerations. Panellists will also explore potential and anticipated next steps for the CHIP.

9:45 – 9:50 **Industry concluding remarks**
Ginny Beakes-Read, Amgen (IFPMA)

9:50 – 9:55 **ICMRA concluding remarks**
Lorraine Nolan, HPRA

ICMRA-industry virtual workshop on
Development of a Pharmaceutical Quality Knowledge Management System
Friday, July 21, 2023
7:00 – 9:00 ET | 13:00 – 15:00 CET
AGENDA

7:00 – 7:05 **ICMRA welcoming remarks**
Lorraine Nolan, HPRA

7:05 – 7:50 **Session 1: Learnings from the collaborative assessment pilot to date**
Moderated by William Lewallen, FDA

Panellists

Asmaa Fouad, EDA
Ian Jackson, MHRA
Moji Christianah Adeyeye, NAFDAC
Ranjit Thomas, FDA
Evdokia Korakianiti, EMA
Larry Lee, FDA
Yasuhiro Kishioka, PMDA
Susan Polifko, FDA

Description: Panellists will further reflect on their experiences and perspectives on the CMC/PACMP pilot, reflect on the views shared by industry during Day 1 of the workshop, and discuss considerations going forward.

7:50 – 8:35 **Session 2: Learning from the collaborative hybrid inspection pilot to date**
Moderated by William Lewallen, FDA

Panellists

Asmaa Fouad, EDA
Ian Jackson, MHRA
Moji Christianah Adeyeye, NAFDAC
Graham Carroll, MHRA
Shinichi Okudaira, PMDA
Brendan Cuddy, EMA
Stelios Tsinontides, FDA
Magda Joseph, Health Canada
Christian Schärer, Swissmedic

Description: Panellists will further reflect on their experiences and perspectives on the CHIP, reflect on the views shared by industry during Day 1 of the workshop, and discuss considerations going forward.

8:35 – 8:55 **Session 3: Future vision, learnings to date, and next steps for the PQ KMS project**
Moderated by Theresa Mullin, FDA

Speakers

Asmaa Fouad, EDA
Ian Jackson, MHRA
Moji Christianah Adeyeye, NAFDAC
Graham Carroll, MHRA
Shinichi Okudaira, PMDA
Susan Polifko, FDA
Ranjit Thomas, FDA
Brendan Cuddy, EMA
Evdokia Korakianiti, EMA
Stelios Tsinontides, FDA
Sau (Larry) Lee, FDA
Magda Joseph, Health Canada
Yasuhiro Kishioka, PMDA
Christian Schärer, Swissmedic

This workshop was jointly organised by ICMRA and IFPMA, including ICH, IPRP, PIC/S, ABPI, BIO, DCVMN, EFPIA, IGBA, JPMA, Medicines Australia, PhRMA, and Vaccines Europe

Description: During this session, regulators will review the portfolio of work underway, pilot learnings to date including key takeaways from the workshop discussions, and other efforts to progress the development of the tools and technology to advance the envisioned capability to enable future reliance.

8:55 – 9:00 **ICMRA concluding remarks**
Emer Cooke, EMA and Chair ICMRA